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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/490,187	01/23/00	CHAUDHARY	P USTD:0680

HM22/0928

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EXAMINER	
MCGARRY,S	
ART UNIT	**PAPER NUMBER**
1635	3

DATE MAILED: 09/28/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

file

Office Action Summary	Application No. 09/490,187	Applicant(s) Chaudhary
	Examiner Sean McGarry	Group Art Unit 1635

☐ Responsive to communication(s) filed on _____ .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-21* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-21* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Claims rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-21 all recite or depend from claims that recite "TAJ". The instant specification discloses an exemplary TAJ gene and protein sequence (SEQ ID NO: 1 and 2) that is a "TAJ" gene or protein. The specification provide no definition of what a TAJ gene or protein is or even for what compound term the acronym TAJ refers. The recitation of "TAJ" does not allow one of skill in the art to know what is encompassed within the claims.

Claims 2-8 and 10-21 are unclear since these claims begin with "A". The instant specification defines "a" to be singular and plural (page 2). Since these claims appear to be directed to singular methods but the specification defines "a" to be both singular and plural it is unclear what is embraced within the claim. Amending these claim to begin --The-- would be remedial.

2. Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant invention is drawn to methods of detecting the presence of or predisposition to an ectodermal disorder via a "TAJ" gene or gene product and to methods of treating "TAJ" associated ectodermal disorders.

The instant specification provides the sequence of one TAJ gene defined by SEQ ID NO: 1 and its respective protein SEQ ID NO: 2. Table 1 of the instant specification provides a number of "TAJ" mutants based on SEQ ID NO: 1 that result in various truncated proteins. It is unclear from the specification how or where these mutants were obtained or constructed. The specification does not teach any other "TAJ" genes or gene products that are not based on SEQ ID NO: 1 or 2. One of skill in the art would not immediately envision the structure of other TAJ genes or gene products that are not based on SEQ ID NO: 1 or 2. The disclosure of sequences based on SEQ ID NO: 1 and 2 does not show that, at the time the application was filed, applicant had possession of the full scope of the claimed invention.

3. Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant invention is drawn to methods of detecting the presence of or predisposition to an ectodermal disorder via a "TAJ" gene or gene product and to methods of treating "TAJ" associated ectodermal disorders.

The instant specification discloses a "TAJ" nucleic acid and protein sequence (SEQ ID NO: 1 and 2). The specification discloses at page 1 that there are over 150 different ectodermal dysplasia syndromes. The specification discloses at page 3 that ectodermal disorders may arise from temporal, developmental, quantitative or qualitative TAJ misexpression and that a wide variety of causalities may effect such misexpression such as genetic lesions or mutations gene itself or direct or indirect TAJ gene regulatory sequences, the misexpression of genes or gene products which may in turn regulate TAJ expression or TAJ function, etc. Table 1 of the instant specification discloses "TAJ" mutants that result in truncated TAJ proteins. This table does not provide any indication what ectodermal dysplasia might be associated with the disclosed mutants and further does not provide any guidance as to how or where these sequences were detected or constructed and are all based on SEQ ID NO: 1 and 2. Further it does not tell one whether these specific mutants are associated with autosomal dominant or recessive ectodermal dysplasia in hetero or homozygous mutants. The instant specification asserts at page 3 that detection can be made directly (detecting protein or nucleic acid), indirectly (detecting specific function of the target) or inferentially (detecting a diagnostic sequence in a genomic or proteomic database). Table 2 discloses "exemplary allele specific TAJ antibodies and hybridization probes". Table 2 indicates specific binding and specific hybridization as "+++". There is no legend that defines what "+++" indicates. Does "+++" represent that there is high level, low level, intermediate binding and relative to what? Table 3 discloses "exemplary agents shown to allele specifically modulate functional expression of a TAJ gene or gene product". Table 3 uses "+++" to designate

modulation. Does "+++" mean increased activity , decreased activity, what level and relative to what? The specification discloses in Example I the differential expression of murine TAJ in mouse embryos and provides a prophetic animal model of Cloustron syndrome. Example II discloses that TAJ activates JNK upon transient over expression of TAJ and discloses a cJun transcriptional activation assay with no results. Example III is a protocol for high throughput TAJ polypeptide-Traf binding interference assay with no results. Example IV appears to be a prophetic example of genomic diagnosis of suspected Cloustron's syndrome. Example V (page 12) is a prophetic example of corrective gene transfer in ectodermal dysplasia. Second example V (page 15) is a prophetic example of localized in vivo genotypic and phenotypic correction.

The instant specification does not provide sufficient guidance or examples that would show by correlation the practice of the instant invention without undue experimentation. Since there are so many (over 150) disease states and little guidance for one of skill in the art to detect or treat such diseases based on the instant specification one would be left to undue trial and error experimentation. For example, the instant invention is based on the association of a TAJ gene and ectodermal dysplasia. The instant specification is sketchy as to the correlation of TAJ and ectodermal dysplasia. No specific examples or discussion is provided that teaches one of skill in the art the role TAJ genes or gene products in and ectodermal dysplastic state. The specification provides tables that appear to be ambiguous in what they disclose. These tables nor the specification provides any guidance as to what ectodermal dysplasia diseases even the mutants of Table 1 are associated. The instant invention appears to be an invitation for one in the art to draw

correlations to any nucleic acid sequence or protein that might be a TAJ to the numerous disease states contemplated. This is not a simple task considering the large number of diseases that manifest in numerous different ways in different cells and involve different biological pathways. For example, ectodermal disorders may arise from temporal, developmental, quantitative or qualitative TAJ misexpression and that a wide variety of causalities may effect such misexpression such as genetic lesions or mutations gene itself or direct or indirect TAJ gene regulatory sequences, the misexpression of genes or gene products which may in turn regulate TAJ expression or TAJ function, etc and one of skill in the art is left to make these correlations themselves. Claim 1 even recites that a correlation must be made. The instant specification has essentially demonstrated that SEQ ID NO:2 activates the JNK pathway upon over expression and that hTAJ is expressed in prostate cell and in fetal kidney cells (fetal kidney cell line) and that TAJ is differentially expressed in murine fetuses. The information provided in the Tables is unclear as to how it provides evidence for TAJ association in ectodermal dysplasia. Without this basic knowledge or correlative evidence or guidance it is unclear how one of skill in the art could practice the claimed invention without undue trial and error experimentation.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean McGarry whose telephone number is (703) 305-7028.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Elliott, can be reached on (703) 308-4003.

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. Papers should be faxed to Art Unit 1635 via the PTO Technology Center Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see C.F.R. 1.6(d)). The Art Unit 1635 FAX number is (703) 308-4242 or (703) 305-3014. NOTE: If Applicant **does** submit a paper by Fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

September 26, 2000

SEAN MCGARRY
PATENT EXAMINER

Technology Center 1600